Claim Objection

Claim 6 was objected to because the claim did not provide the expansion for the abbreviation "CYB5RP." Applicants have amended this claim to include the phrase "cytochrome b5-related protein" as suggested in the Office Action. Withdrawal of this objection is respectfully requested.

Claim Rejection under 35 U.S.C. §101

As stated in the Office Action, claim 3 was rejected because it claimed non-statutory subject matter. Applicants have amended this claim to include the phrase "an isolated" with reference to the DNA molecule as suggested in the Office Action. Withdrawal of this rejection is respectfully requested.

Claim Rejections under 35 U.S.C. §112, second paragraph

As stated in the Office Action, claim 3 was rejected as being indefinite with respect to the phrase "under stringent conditions." Applicants have amended this claim to include the phrase "conditions of high stringency" as suggested in the Office Action.

As stated in the Office Action, claim 6 was rejected as being indefinite with respect to the phrase "delta-6 fatty acid desaturase activity." Applicants respectfully traverse this rejection as it is not required that an applicant limit an invention to one utility as suggested in the Office Action. As the Training Materials provided by the USPTO for 35 U.S.C. §112 Rejections Not Based on Prior Art ("112 Training Materials") make clear, the essential question under 35 U.S.C. §112, second paragraph, is whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. Section A of 112 Training Materials (emphasis added). Only when the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, is a rejection under this section appropriate. MPEP 2173.02. In claim 6, applicants are claiming a novel isolated gene and a splice variant by its amino acid sequence. There can be no more precise way to claim such an invention than by its unique amino acid sequence. The Courts have concurred and have held that absence of a limitation does not render an invention as indefinite. See In re Fisher, 427 F.2d 833, 166 U.S.P.Q. 18,23 (CCPA 1970) (emphasis in original). To infer that one must include a function, as suggested in the Office Action, to render a claim definite is beyond the requirements under this section. While an applicant may define something

by what it does, rather than by what it is, MPEP 2173.01, there is no mandate that a stated function must be included in a claim to meet the definiteness requirements of this section, where the invention can be clearly and precisely defined by its structure or specific ingredients, i.e. the sequence.

As stated in the Office Action, claim 9 was rejected as being indefinite with respect to the phrase "amino acid substitutions." Applicants have amended claim 9, and claim 7 from which it depends, to more distinctly claim the invention therein.

Withdrawal of these rejections is respectfully requested.

Claim Rejections under 35 U.S.C. §112, first paragraph

As stated in the Office Action, claims 3 and 11 were rejected under 35 U.S.C. §112, first paragraph, because the Specification does not provide enablement for any DNA molecule comprising at least 18 contiguous nucleotides which hybridize to any of the cited polynucleotides of claims 3 and 11 under stringent conditions. The Office Action does acknowledge that the Specification does provide enablement for DNA with SEQ ID NOS: 1 or 2, SEQ ID NO: 2 lacking positions 1,019-1,054; positions 71-1,405 of SEQ ID NO:2 or positions 71-1,405 of SEQ ID NO:2 lacking positions 1,019-1,054 as encoding a polypeptide having a delta 6-fatty acid desaturase activity and an amino acid sequence of SEQ ID NO:3 or amino acid sequence SEQ ID NO:3 lacking amino acids 317-328. The Office Action further sets forth the view with respect to claims 3 and 11 that the claims are so broad as to encompass any DNA from any source, irrespective the fact whether it encodes the polypeptide with SEQ ID NO:3 but which can hybridize to the above polynucleotides under any stringent conditions. Applicants respectfully traverse this rejection. Notwithstanding, in an effort to advance prosecution, Applicants have amended claim 3 to more distinctly define the claimed invention.

To satisfy the enablement requirement of §112, first paragraph, all that is necessary is that one skilled in the art be able to practice the claimed invention. Further, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See for example, In re Fisher, cited above. Applicants have amended claim 3 to include the phrase "that hybridize under conditions of high stringency" to define the invention therein as those DNA molecules that hybridize to the cDNA sequences that encode CYB5RP or its splice variant under a particular set of conditions. Such conditions are explicitly laid out on pages 9 and 10 of the specification and as such, clearly provide guidance to those of ordinary skill in the art. Contrary to the assertions made in the Office Action, claim 3 is not directed to any DNA

molecule which hybridize to the polynucleotides of claim 2. Rather claim 3 is directed to those DNA molecules that hybridize to specified cDNA's under very specific conditions. While it is not entirely clear as to the scientific basis for this rejection, the Office Action seems to infer that specifying the source of the DNA, the desaturase functionality or even the purpose for which such DNA molecules are intended would in some way enable those skilled in the art to practice the invention enabled by the Specification. Notwithstanding that the Office Action is entirely devoid of any cited reference or rationale for why a person of skill in the art would not be able to practice the invention as claimed given the explicit stringency conditions set forth in the Specification, Applicants submit that those DNA molecules encompassed by this claim are reasonably correlated with the disclosure provided such that one skilled in the art, knowing the sequence and the conditions, would be able to practice the invention.

Applicants have cancelled claim 11, rendering the objection to this claim moot.

Claims 6-9 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that Applicants had possession of the claimed invention at the time the instant application was filed. As Applicants understand this rejection, claims 6-9 were rejected because Applicants have not made or specifically described the genus of polypeptides modified by at least one amino acid substitution of SEQ ID NO:3. Applicants respectfully traverse this rejection. Notwithstanding, in an effort to advance prosecution, Applicants have amended claim 7 and, in turn, claims 8 and 9 which depend therefrom, to include the phrase "wherein said substitution still retains substantially the same biological activity as CYB5RP" to further clarify that only those substitutions which result in the claimed functionality are included with this claim. One skilled in the art having the amino acid sequence (SEQ ID NO:3), the description of the substitutions on pages 11 and 12 of the Specification, along with the definition on page 6 of "substantially the same biological activity as CYB5RP," would readily conclude that the Applicants had possession of the claimed invention at the time the instant application was filed.

Withdrawal of these rejections is respectfully requested.

Claim Rejection under 35 U.S.C. §102

Claims 1-5 and 11 were rejected under 35 U.S.C. §102(a) as being anticipated by Petrukhin et al. While not explicitly stated as such, the Office Action appears to assert that the claimed invention is anticipated on the basis of three segments, representing approximately 1500 nucleotides, of a retina-specific gene called VMD2. Applicants respectfully traverse this

rejection on the basis that each and every element of the claimed invention is not disclosed in the cited prior art.

To anticipate a claimed invention, a reference must unequivocally disclose each element of the claimed invention, as well as the claimed combination of elements. "Anticipation means the disclosure of the prior art of a thing substantially identical with the claimed invention." Idacon Inc. v. Central Forest Products, 3 USPQ2d 1079 (E.D. OK 1986). All elements must be found in the reference. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As the Court further stated in Idacon, "A reference which provides nothing more than a starting point for further experiments which might possibly lead in the direction of the invention would not qualify as an anticipation." 3 USPQ2d at 1089.

Applicants respectfully point out that the instant invention is directed to a cytochrome b5-related protein (CYB5RP). The genomic DNA (SEQ ID NO:1), set forth in Fig 2A-G, has a sequence of 18,402 nucleotides which defines a gene having 12 exons (underlined regions). The cDNA (SEQ ID NO:2) encodes a 445 amino acid (SEQ ID NO:3), set forth in Fig 3A-C, with amino acids 1-102 representing the cytochrome b5 region and three HIS BOX motifs characteristic of this type of protein. Applicants have also cloned a splice variant of CYB5RP, which comprises SEQ ID NO:3 lacking positions 317-328, that is, when an alternately spliced exon 8 is used, a CYB5RP protein of 433 amino acids is produced. On the contrary, the gene described in the Petrukhin reference encodes a 585 amino acid protein comprising a total of 11 exons with two splice variants of exon 7 and a genomic sequence of roughly 16,000 nucleotides. The three overlapping segments which were specifically cited in the Office Action, may have sequence identity with a portion of the claimed sequence (the most extensive sequence only aligns with 600 nucleotides of the claimed sequence), but do not comprise the total sequence and, as such, are not "substantially identical with the claimed invention." More importantly, the specific segments cited do not disclose or even align with those segments set forth in claim 2, i.e. position 1,019-1,054 or 71-1,405. Rather, they correspond to positions 1-600 (95,890-96,489), 1-402 (113,889-114,290) and 1-501 (104,889-105-389), respectively.

Thus, it is respectfully submitted that the cited reference does not anticipate the claimed invention and Applicants request that the Examiner reconsider and withdraw this rejection.

CONDITIONAL PETITION

Applicant hereby makes a Conditional Petition for any relief available to correct any defect in connection with this filing, or any defect remaining in this application after this filing. The Commissioner is authorized to charge deposit account 13-2755 for the petition fee and any other fee(s) required to effect this Conditional Petition.

CONCLUSION

In view of the foregoing amendments and remarks, it is seen that the grounds of rejections have been overcome and that Claims 1-9 are in proper condition for allowance. Accordingly, Applicants respectfully request that all of the rejections of record be withdrawn and a Notice of Allowance be forwarded to the Applicants. The Examiner is invited to contact Applicant's Attorney at the telephone number given below, if such would expedite the allowance of this application.

Respectfully submitted,

By Joan E. Switzer

Joan E. Switzer
Reg. No. 34,740
Attorney for Applicant

MERCK & CO., INC.
P.O. Box 2000
Rahway, New Jersey 07065-0907
(732) 594-5616

Date: 3/4/03

Marked Version of Claims to Show Changes

1. A recombinant DNA molecule encoding a polypeptide having the amino acid sequence of SEQ.ID.NO.:3.

2. A recombinant DNA molecule comprising a nucleotide sequence selected from the group consisting of:

SEQ.ID.NO.:1;
SEQ.ID.NO.:2;
SEQ.ID.NO.:2 lacking positions 1,019-1,054;
positions 71-1,405 of SEQ.ID.NO.:2; and
positions 71-1,405 of SEQ.ID.NO.:2 lacking positions 1,019-1,054.

3. An isolated DNA molecule comprising a sequence that hybridizes under [stringent] conditions of high stringency to a [the] DNA molecule [of claim 2] selected from the group consisting of:

SEQ ID NO: 2;
SEQ ID NO: 2 lacking positions 1,019-1,054;
positions 71-1,405 of SEQ ID NO: 2; and
positions 71-1,405 of SEQ ID NO:2 lacking positions 1,019-1,054.

4. An expression vector comprising the DNA of claim 1.

5. A recombinant host cell comprising the DNA of claim 1.

6. A cytochrome b5-related protein (CYB5RP) [protein], substantially free from other proteins, having an amino acid sequence selected from the group consisting of SEQ.ID.NO.:3 and SEQ.ID.NO.:3 lacking positions 317-328.

7. The CYB5RP protein of claim 6 containing [a single] at least one amino acid substitution, wherein said substitution still retains substantially the same biological activity of CYB5RP.

8. The CYB5RP protein of claim 7 where [the] said substitution is a conservative substitution.

9. The CYB5RP protein of claim [6] 7 wherein said [containing] amino acid substitution[s where the substitutions do] does not occur in a position[s] where the amino acid present in CYB5RP at [those] that position[s] is also present in the corresponding position in the delta 6 desaturase from sunflower, when CYB5RP and the delta 6 desaturase from sunflower are aligned by BLASTP analysis, or where the substitution[s do] does not occur in a position[s] where the amino acid present in CYB5RP at [those] that position[s] is also present in the corresponding position in the delta 6 desaturase from *Synechocystis*, when CYB5RP and the delta 6 desaturase from *Synechocystis* are aligned by BLASTP analysis, or where the substitution[s do] does not occur in a position[s] where the amino acid present in CYB5RP at [those] that position[s] is also present in the corresponding position in the delta 6 desaturase from borage, when CYB5RP and the delta 6 desaturase from borage are aligned by BLASTP analysis.

[10. An antibody that binds specifically to the CYB5RP protein of claim 6.]

[11. A DNA or RNA oligonucleotide probe comprising at least 18 contiguous nucleotides of at least one of the sequences of claim 2.]

PATENT
CASE NO. 20267P

1652 #

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner for Patents
Washington, D.C. 20231

In re application of: PETRUKHIN, ET AL.
Serial No. 09/806,088
Filed July 13, 2001
Group Art Unit 1652
Examiner Rao
For: DELTA 6 FATTY DESATURASE

Transmitted herewith is an amendment in the above-identified application.

☐ No additional fee is required.

☒ The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2) Claims remaining after amendment	(3)	(4) Highest Number Previously Paid For	(5) Present Extra	(6) Rate	(7) Additional Fee
Total Claims	* 9	-	** 20 =	0 X	$18	= 0.00
Independent Claims	* 4	-	*** 3 =	1 X	$84	= 84.00
Multiple Dependent Claims					$280 ****	=
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT →			84.00

* If the entry in Column 2 is less than the entry in Column 4, write "0" in Column 5.
** If the "Highest Number Previously Paid For" in this space is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" in this space is less than 3, write "3" in this space.
**** Add this fee only if application is amended to include multiple dependent claims (regardless of number) and no multiple dependent claims were originally filed.

Charge $ 84.00 to Deposit Account No. 13-2755. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2755. A duplicate copy of this sheet is enclosed.

Respectfully,

By: Joan Switzer
Attorney for Applicant(s)
Reg. No. 34,740

MERCK & CO., INC.
Patent Dept., RY60-30
P.O. Box 2000
Rahway, N.J. 07065-0907

(732) 594-5616

Date: March 4, 2003

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK & CO., INC.
By Nancy E. Yorke Date 3/4/03

IN DUPLICATE